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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/517,846 | 12/29/2005 | Moshe Shoham | Q85350 | 9015 |

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| EXAMINER | |
|---|---|
| REMALY, MARK DONALD | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3737 | |

| NOTIFICATION DATE | DELIVERY MODE |
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| 06/28/2010 | ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/517,846 | SHOHAM ET AL. | |
| | Examiner | Art Unit | |
| | Mark Remaly | 3737 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *1-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 1-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/29/2010.

2. Applicant's election without traverse of Group II in the reply filed on 03/29/2010 is acknowledged.

### *Double Patenting*

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 19-43 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,837,892 in view of Mittelstadt et al. (US Pat. No. 6,322,567 B1). Although the claims are not identical, U.S. Patent No. 6,837,892 does claim a surgical robot, attachment member and controller for aligning the surgical tool with the target bone using images. Although U.S. Patent No. 6,837,892 does not claim the use of two different types of registration, Mittelstadt et al. ('567) does teach the use of anatomical features and fiduciary markers for registration (see column 2, lines 37-53; and column 9, lines 41-67). It would be obvious to one of ordinary skill in the art to combine U.S. Patent No. 6,837,892 with Mittelstadt et al. ('567) for the purpose of providing robotically guided orthopedic surgery using real time feedback of imaging methods.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 19-30, 37 and 40-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claims 19-30 and 40-43, the claims are directed to an imaging system, however, no structure has been

set forth to provide means for imaging in the claims. Claim 22 recites the limitation "said imaging system" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim; it is only inferentially set forth in the preamble. Claim 29 recites the limitation "said edge detection routine" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim. Claim 37 is indefinite in that it is unclear as to what claim it depends from. Claims 40-42 are indefinite in that claim attempts to further define an unclaimed element.

***Claim Rejections - 35 USC § 101***

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 31-33, 37, 38 and 42 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims are 31-33, 37 and 38 rejected under 35 USC 101 because these are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to a particular machine. See Diamond v. Diehr, 450 U.S. 175, 184 (1981) (quoting Benson, 409 U.S. at 70); Parker v. Flook, 437 U.S. 584, 588 n.9 (1978) (citing Cochrane v. Deener, 94 U.S. 780, 787-88 (1876)). See also In re Bilski (Fed Cir, 2007-1130, 10/30/2008) where the Fed. Cir. held that method claims must pass the "machine-or-transformation test" in order to be eligible for patent protection under 35 USC 101. Claim 42 is rejected under 101 because it claims the body part as part of the claimed invention by positively reciting the robot as being mounted on the bone.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 19, 20, 24, 25, 27, 31, 33, 34, 36 and 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mittelstadt et al. (US Pat. No. 6,322,567 B1) in view of Matsen, III et al. (US Pat. No. 5,690,635).

Mittelstadt et al. ('567) teach a system for determining the initial spatial relationship between the surgical robotic arm and the bone can be accomplished in a variety of ways using radio-opaque marker pins. For example, prior to surgery, the marker pins are attached to the bone and a pre-surgical image of the bone with the marker pins attached is taken. The pre-surgical image can preferably be generated by computerized tomography (CT), digital radiography, or the like. From the pre-surgical image, the spatial relationship of the bone with respect to the marker pins can be

determined, (ie: the position and orientation of the bone can be determined by knowing the position and orientation of the marker pins). Thereafter, the surgical robotic arm is registered to the bone by being moved to contact each of the marker pins in turn. As such, the position of each of the marker pins will be sequentially recorded in terms of the surgical robotic arm's co-ordinate system, thereby registering the surgical robotic arm to the bone (see column 2, lines 37-53). Tracking translational and rotational movements of the bone with the bone motion detector may include securing a distal end of a six degree of freedom passive mechanical arm to the bone and tracking movement of the passive mechanical arm as it moves with the bone (see column 4, lines 3-8).

Referring to Figure 1, robotic workstation 10 comprises a robot 11 and a user interface 13. Robot 11 further comprises a surgical robotic arm 20, a passive mechanical arm bone motion detector 40 and a bone fixator 70 (see column 7, lines 46-49). A bone coupling device 48 which is preferably percutaneously attached to bone 50 firmly anchors distal end 47 of passive mechanical arm 40 to bone 50 (see column 8, lines 15-18). The invention provides a method of tracking and compensating for bone motion when surgical robotic arm 20 operates on bone 50 such that the correct positioning of surgical robotic arm 20 with respect to bone 50 can be maintained during the cutting operation (see column 8, lines 43-48). Should such motion be detected during the initial registration of surgical robotic arm 20 to bone 50, the registration process can be automatically terminated such that the bone can be re-secured into position before the initial registration process is re-initialized. However, having passive mechanical arm 40 connected to bone 50 to monitor bone motion during the initial registration of surgical robotic arm 20 to bone 50 allows the initial registration process to

be continuously updated, even during bone motion, such that it is not necessary to stop and recommence the initial registration procedure (see column 9, lines 10-20).

As an alternative to using marker pins 51, 52, and 53 on bone 50, to register surgical robotic arm 20 to bone 50, it is also possible to use an optical, mechanical or ultrasound imaging system in conjunction with a pre-surgical image of bone 50 to determine the position and orientation of surgical robotic arm 20 with respect to bone 50 by the recognition of anatomical features thereon as described above. For example, sensor 80 may preferably comprise an optical or ultrasound system which determines the position and orientation of bone 50 by sensing anatomical features on the bone. Surgical robotic arm 20 can be registered to bone 50 without the use of marker pins 51, 52 and 53 by using passive mechanical arm 40 to generate a digitized bone data set by taking surface position measurements of bone 50 with passive mechanical arm 40, and transforming the bone image data set into the coordinate system of surgical robotic arm 20 by performing a best fit calculation between coordinates of a pre-surgical bone image data set and corresponding coordinates of the digitized bone data set (see column 9, lines 41-67).

Although Mittelstadt et al. ('567) does not explicitly teach the use of alignment with drill holes, Matsen, III et al. ('635) from the same field of endeavor do teach determining the position and orientation of a drill guide relative to the desired position of a prosthesis (see column 8, lines 38-40; and figure 27). Figure 24 illustrates a drill guide 252 used in the present system. The drill guide includes an attachment flange 254, a reference plate 256, a threaded bit guide 258, and pin guides 260. The reference plate is perpendicular to the axis of the bit guide 258. The attachment flange of the drill guide is similar to that of the saw guide, with the identification pattern identifying it as a drill

guide. The attachment flange is connected to the coupling block by a thumbscrew (not shown). Preferably the bores are made after the distal cut, but that is not required. The bit guide axis need only be aligned with the bore axis and the guide positioned near the bone to successfully complete the drilling task (See column 26, lines 18-32).

It would be obvious to one of ordinary skill in the art to combine the two registration methods of Mittelstadt et al. with the drilling guide and alignment methods of Matsen, III et al. for the purpose of providing robotically guided orthopedic surgery using real time feedback of imaging methods.

11. Claims 21, 28, 30, 37 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mittelstadt et al. (US Pat. No. 6,322,567 B1) in view of Matsen, III et al. (US Pat. No. 5,690,635) as applied to claims 19, 20 and 31 above, and further in view of Kienzle, III (US Pat. No. 6,718,194 B2).

Mittelstadt et al. ('567) in view of Matsen, III et al. ('635) teach the system and method as discussed above but do not explicitly teach alignment when a target hole has a minimum elliptical shape. However, Kienzle, III ('194) from the same field of endeavor do teach a method where an intraoperative x-ray machine (C-arm) is repeatedly fired and reoriented until it is exactly aligned with the transverse holes as evidenced by x-ray images displaying the holes as "perfect circles" (see column 1, lines 20-24). The invention provides a computer assisted surgery system for positioning an instrument relative to a portion of a surgical implant. More specifically, it assists a surgeon in drilling a hole through a long bone and through transversely oriented holes in an intramedullary rod (IM rod) during a fracture fixation procedure regardless of deformation of the IM rod. The invention provides a technique and apparatus for accurately displaying the trajectory of the drill relative to the holes of the IM rod and a technique and apparatus

for using x-ray images of the IM rod to accurately determine the locations of the holes. The system includes a tracked adapter attached to the IM rod and a drill guide, both of which have their poses determined by the localizer. With the IM rod inserted in a long bone, and the tracked adapter attached to the exposed end of the IM rod the pose of the adapter and the IM rod are measured by the localizing device. Two approximately orthogonal x-ray images are then obtained of the IM rod in the vicinity of the holes. Image processing techniques are used to accurately determine the location of the IM rod from the x-ray images and an adjusted pose is calculated for the IM rod. A graphic representation of the drill trajectory is displayed superimposed over the images of the IM rod and over a graphic representation of the IM rod, in order to assist the surgeon in placing the drill in the proper position relative to the IM rod holes (see column 2, lines 29-60). It would be obvious to one of ordinary skill in the art to combine the invention of Mittelstadt et al. in view of Matsen, III et al. with the alignment methods of Kienzle, III for the purpose of providing robotically guided orthopedic surgery using real time feedback of imaging methods.

12. Claims 22, 23 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mittelstadt et al. (US Pat. No. 6,322,567 B1) in view of Matsen, III et al. (US Pat. No. 5,690,635) as applied to claims 19 and 31 above, and further in view of Glassman et al. (US Pat. No. 5,408,409).

Mittelstadt et al. ('567) in view of Matsen, III et al. ('635) teach the system and method as discussed above but do not explicitly teach camera calibration functions. However, Glassman et al. ('409) from the same field of endeavor do teach camera calibration functions (see column 4, lines 48-52). It would be obvious to one of ordinary skill in the art to combine the invention of Mittelstadt et al. in view of Matsen, III et al.

with the calibration methods of Glassman et al. for the purpose of providing properly aligned imaging registration.

13. Claims 26 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mittelstadt et al. (US Pat. No. 6,322,567 B1) in view of Matsen, III et al. (US Pat. No. 5,690,635) as applied to claims 25 and 34 above, and further in view of Lang et al. (US Pat. No. 6,690,761).

Mittelstadt et al. ('567) in view of Matsen, III et al. ('635) teach the system and method as discussed above but do not the use of a Hough Transform method. However, Lang et al. ('761) from the same field of endeavor do teach a Hough Transform method (see column 4, lines 8-14). It would be obvious to one of ordinary skill in the art to combine the invention of Mittelstadt et al. in view of Matsen, III et al. with the Hough Transform method taught by Lang et al. for the purpose of providing properly weighted bone detection.

14. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mittelstadt et al. (US Pat. No. 6,322,567 B1) in view of Matsen, III et al. (US Pat. No. 5,690,635) as applied to claim 19 above, and further in view of Navab et al. (US 2002/0094189 A1).

Mittelstadt et al. ('567) in view of Matsen, III et al. ('635) teach the system and method as discussed above but do not the use of a Canny edge detection with sub-pixel localization. However, Navab et al. ('189) from the same field of endeavor do teach a Canny edge detection with sub-pixel localization (see ¶0051). It would be obvious to one of ordinary skill in the art to combine the invention of Mittelstadt et al. in view of Matsen, III et al. with the Canny edge detection with sub-pixel localization taught by

Navab et al. for the purpose of providing a method of prediction correction in image analysis and anatomical feature detection.

15. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mittelstadt et al. (US Pat. No. 6,322,567 B1) in view of Matsen, III et al. (US Pat. No. 5,690,635) in view of Kienzle, III (US Pat. No. 6,718,194 B2) as applied to claim 37 above, and further in view of Navab et al. (US 2002/0094189 A1).

Mittelstadt et al. ('567) in view of Matsen, III et al. ('635) in view of Kienzle, III ('194) teach the system and method as discussed above but do not the use of a Canny edge detection with sub-pixel localization. However, Navab et al. ('189) from the same field of endeavor do teach a Canny edge detection with sub-pixel localization (see ¶0051). It would be obvious to one of ordinary skill in the art to combine the invention of Mittelstadt et al. in view of Matsen, III et al. in view of Kienzle, III with the Canny edge detection with sub-pixel localization taught by Navab et al. for the purpose of providing a method of prediction correction in image analysis and anatomical feature detection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Remaly whose telephone number is (571) 270-1491. The examiner can normally be reached on Monday - Friday 7:30am-5:00pm, alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Remaly/
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737